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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,368	03/25/2004	Andreas Bergmann	121778-40308757	4724
43569	7590	07/05/2006	EXAMINER	
MAYER, BROWN, ROWE & MAW LLP 1909 K STREET, N.W. WASHINGTON, DC 20006			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/808,368	Applicant(s) BERGMANN ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-7 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-gastric-releasing peptide (proGRP), classified in class 435, subclass 7.1.

Group II. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-endothelin-1 peptide (proEND), classified in class 435, subclass 7.1.

Group III. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-brain-natriuretic peptide (pro-BNP), classified in class 435, subclass 7.1.

Group IV. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-atrial-natriuretic peptide (proANP or pro-ANF), classified in class 435, subclass 7.1.

Group V. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-leptin, classified in class 435, subclass 7.1.

Group VI. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-neuropeptide-Y, classified in class 435, subclass 7.1.

Group VII. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-somatostatin, classified in class 435, subclass 7.1.

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Group VIII. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-neuropeptide-YY, classified in class 435, subclass 7.1.

Group IX. Claims 1-5, 7, drawn to a method for the differential-diagnostic early detection and detection of a pro-adrenomedullin (pro-ADM), classified in class 435, subclass 7.1.

Group X. Claim 6, drawn to a method for the differential-diagnostic early detection of dipeptidyl-peptidase IV, classified in class 435, subclass 7.1.

*These claims 1-5, 7, embrace multiple patentably distinct embodiments.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-X are independent and distinct, each from the other, because the methods are practiced with materially different products which are structurally and chemically different, the novelty of the inventions lying in the products being detected and not the processes. The only feature in common in the instant inventions is “a method for the differential-diagnostic early detection”, which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as IL-1. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products to be detected in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of pro-GRP with sepsis would not necessarily reveal art for an association of pro-ADM with sepsis. Similarly, a search

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of the literature with any of pro-END, pro-BNP, pro-ANF or pro-leptin would not necessarily reveal art for an association of pro-GRP with sepsis.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.

Primary Examiner

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June 20, 2006